PATENT APPLICATION

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Klaus Hellerbrand et al.

Appln. No.: 10/598.698

Filing Date: September 8, 2006

Title: COATED IMPLANTS, THEIR MANUFACTURING AND USE

THEREOF

Examiner:

Group Art Unit:

1618 9077

Confirmation No.: Customer No .

25764

Docket No.:

79650 - 341358

U.S. PATENT AND TRADEMARK OFFICE Customer Service Window, Mail Stop AMENDMENT

Randolph Building 401 Dulany Street Alexandria, VA 22314 I CERTIFY THAT, ON MARCH 23, 2007, THIS PAPER IS BEING DEPOSITED WITH UNITED PARCEL SERVICE, AS UPS GROUND, IN A BOX ADDRESSED TO: U.S. PATENT AND TRADEMARK OFFICE, CUSTOMER SERVICE WINDOW, MAIL STOP AMENDMENT, RANDOLPH BUILDING, 401 DULANY STREET, ALEXANDRIA, VA 22314.

amlu

INFORMATION DISCLOSURE STATEMENT

The materials enclosed herewith are provided to the Examiner for consideration during the examination of the cited patent application. Consideration of each of the documents listed on the attached SB/08 form(s) is respectfully requested.

This Information Disclosure Statement is being filed before the receipt of an Office Action on the merits. No fee is believed to be necessary. However, should any fee be required, the Commissioner is authorized to charge our Deposit Account No. 06-0029 and is requested to notify us of the same.

Respectfully submitted.

FAEGRE & BENSON LLP

By:

Paul W. Busse, Reg. No. 32,403

612/766-7046

Customer No.: 25764

Dated: March 23, 2007

F&B (10-06) SB/08a (07-06) Sufficitute for form 1449A/PTO Complete if Known A TRADE Application Number 10/598,698 INFORMATION DISCLOSURE Filing Date March 9, 2005 STATEMENT BY APPLICANT First Named Inventor Klaus Hellerbrand Art Unit (Use as many sheets as necessary) Examiner Name Sheet of 5 Attorney Docket Number 79650 - 341358

			U.S. PATENT	DOCUMENTS	
Examiner Cite		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant
Initials *	No.1	Number - Kind Code ² (// known)	MM-DD-YYYY	Applicant of Cited Document	Figures Appear
		US- 4,051,598	10-04-1977	Sneer	
		US- 4,599,D85	D7-D8-1986	Riess et al.	
		US- 4,882,196	11-21-1989	Shimamune et al.	
	$\overline{}$	US- 5,011,691	04-30-1991	Oppermann et al.	
		US- 5,258,029	11-02-1993	Chu et al.	
		US- 5,266,683	11-30-1993	Oppermann et al.	
		US- 5,344,654	09-06-1994	Rueger et al.	
		US- 5,697,997	12-16-1997	Aronsson et al.	
		US- 5,934,287	08-10-1999	Hayashi et al.	
		US- 6,113,993	09-05-2000	Gao et al.	
		US- 6,129,928	10-10-2000	Sarangapani et al.	
		US- 6,312,472 B1	11-06-2001	Hall et al.	
		US- 8,322,728 B1	11-27-2001	Brodkin et al.	
		US- 6,419,708 B1	07-16-2002	Hall et al.	
		US- 2003/0204239 A1	10-30-2003	Carlyle et al.	
		US- 6,994,549 B2	02-07-2006	Brodkin et al.	

		FOREIGN	PATENT DO	CUMENTS		
Examiner Cite		Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages Or	
Initials*	No.1	Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Figures Appear	T°
		EP 0382367 B1	02-28-1996	Stryker Corporation		
		EP 0372031 B1	09-11-1996	Stryker Corporation		
		EP 0369713 B1	04-08-1993	Kyoto University		
		EP 0448704 B1	06-17-1998	Stryker Corporation		
		EP 0487948 B1	01-03-1996	Siftelsen Centrum for Oral Biologi		
		EP 0478532 A1	04-01-1992	Dr. David Thomas		
		EP 0548385 B1	03-31-1999	Kabushiti Kaiysa Advance		
		EP 0575555 B1	07-18-2001	Curis, Inc.		
		EP 0584283 B1	12-15-1991	Intermedics/Orthopedics/ Denver Inc.		
		EP 0601106 B1	D5-17-2000	Creative Biomolecules, Inc.		
		EP 0601135 B1	11-02-2005	Curis, Inc.		
	I	EP 0643767 B1	07-22-1998	Stryker Corporation		
		EP 0646022 B1	09-28-2005	Stryker Corporation		
		EP 0657146 B1	D4-D1-1998	Nobel Biocare AB		
		EP 0679097 B1	D5-28-1997	Genetech, Inc.		
		EP 0714865 B1	D1-22-2003	Stryker Corporation		
		EP 0723013 B1	06-18-2006	Stryker Corporation		
		EP 0739191 B1	D1-D9-2002	Nobel Biocare AB		
		EP 0806211 B1	10-23-2002	IsoTis N.V.		

Examiner Signature	/Dennis Heyer/	Date Considered	05/08/2009
-----------------------	----------------	--------------------	------------

EXAMISE! Intil if aftered consisted, where or not claim is in undermote any METP RD, then be repul; stated in a northward and or continuous and of consistent, include soop of the many with a continuous in a popular. Application is used in the continuous and or con

fb.us.1755221.D1

OIPE

F&B (10-06) SB/08a (07-06)

					FAB (10-00) SB/088 (07-00		
Substitute for form 1449A/PTO				Complete if Known			
				Application Number	10/598,698		
INFC	RMATION	DIS	CLOSURE	Filing Date	March 9, 2005		
STA.	TEMENT B	YA	PPLICANT	First Named Inventor	Klaus Hellerbrand		
				Art Unit			
(Use as many sheets as necessary)			necessary)	Examiner Name			
Sheet	2	of	5	Attorney Docket Number	79650 - 341358		

	U.S. PATENT DOCUMENTS						
Examiner	Cite	Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where		
Initials No.	No.	Number - Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear		
		US-					

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or	T ⁶	
miliais		Country Code ³ - Number ⁴ - Kind Code ⁵ (if known)	MM-DD-YYYY		Relevant Figures Appear		
_		EP 0812207 B1	11-02-2000	Stryker Corporation			
		EP 0972520 B1	08-17-2005	Biopharm.			
		EP 1150725 B1	06-01-2005	SDGI Holdings, Inc.			
		EP 1220693 B1	12-08-2004	Genetics Inst., Inc.			
		EP 1221484 A2	07-10-2002	Stryker Corporation			
		EP 1223990 B1	07-28-2004	Genetics Inst., Inc.			
		EP 1225225 A2	07-24-2002	Stryker Corporation			
		EP 1251889 B1	02-07-2003	IsoTis N.V.			
		WO 198800205	01-14-1988	Genetics Institute, Inc.			
		WO 1992000382	01-09-1992	Carnegie Institution of Washington			
		WO 1993016099	08-19-1993	Biopharm			
		WO 1993000432	01-07-1993	Genetics Institute, Inc.			
		WO 1994010203	05-11-1994	Creative Biomolecules, Inc.			
		WO 1994015949	07-21-1994	Johns Hopkins University School of Medicine			
	L	WO 1994015966	07-21-1994	Johns Hopkins University School of Medicine			
		WO 1994021681	09-29-1994	Johns Hopkins University School of Medicine			
		WO 1994026892	11-24-1994	Genetics Institute, Inc.			
		WO 1994026893	11-24-1994	Genetics Institute, Inc.			
		WO 1995001801	01-19-1995	Johns Hopkins University School of Medicine			
		WO 1995010539	04-20-1995	Johns Hopkins University School of Medicine			
		WO 1995013101	05-18-1995	Klaas DeGroot			
	L	WO 1995016035	06-15-1995	Genetics Institute, Inc.			
		WO 1995033830	12-14-1995	Genetics Institute, Inc.			
		WO 1996001316	01-18-1996	Biopharm			
		WO 199601845	01-25-1996	Johns Hopkins University School of Medicine			
		WO 199610370	04-11-1996	Nobelpharma AB			
		WO 1996014335	05-17-1996	The Department of Health and Human Services, US Govt.			

Examiner Signature	/Dennis Heyer/	Date Considered	05/08/2009

"EXAMINED: Initial II detunce consistency whether or not clation is in codemness with MEPE 500 Days fire intemph clation ir not in personnesses and MEPE 500 Days fire intemph clation ir not in personnesses and many consistent inclinate copy of this form when the commentation to explored." Applicant surprise ceitable dissipation funding to Glorison in Sea Kinsto Codes of USFTO Patent Documents in <u>www.upsto.gov</u> or MEPE 901.04. "Enter Office that issued the document, by the two-letter code (WVPO Standard ST 33," "for Japanese patent foodcomment, by indication of the year of the import out precede the setting number of the patent document, but indicated contains in the contains of the part of the Emport out preceded the setting number of the patent document. Visit of document by the appropriate symbols as indicated on the document under VVPO Standard ST. 16 if possible." Applicant is to piece a check mark here if English language SEMIO TO. Commistationer for Patents, Po. 80s. 1456, Naturafies, VA. 2013-1450.

OCHO TO: COMMISSIONER TOF PAURILS, P.O. BOX 1400, Alexandria, VA 22313-1400

					F&B (10-06) SB/08a (07-06		
Substitute for form 1449A/PTO				Complete if Known			
				Application Number	10/598,698		
INFO	RMATION	DIS	CLOSURE	Filing Date	March 9, 2005		
STAT	TEMENT B	Y A	PPLICANT	First Named Inventor	Klaus Hellerbrand		
				Art Unit			
(Use as many sheets as necessary)		Examiner Name					
Sheet	3	of	5	Attorney Docket Number	79650 - 341358		

U.S. PATENT DOCUMENTS						
Exeminer	Cite	Document Number	Publication Dete	Name of Patentee or	Pages, Columns, Lines, Where	
Initials No 1	No.	Number - Kind Code ² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevent Passages or Relevant Figures Appear	
		us-				

		FOREIGN	PATENT DO	CUMENTS				
Examiner Initials*	Cite No.	Cite Foreign Patent Document No.1 Country Code ³ - Number ⁴ - Kind Code ⁵ (# known)		Dete		Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Pessages Or Relevant Figures Appear	T ⁰
	-	WO 1996036710	MM-DD-YYYY		Relevant Figures Appear			
	├—		11-21-1996	Genetics Institute, Inc				
	<u> </u>	WO 1997041273	11-06-1997	Flametal S.P.A>				
		WO 1998043550	10-08-1998	James A. Davidson				
		WO 1998048862	11-05-1998	Jan Hall et al.				
		WO 2000072776 A1	12-07-2000	Nobel Biocare AB				
		WO 2000072777 A1	12-07-2000	Nobel Biocare AB				
		WO 2000072778 A1	12-07-2000	Nobel Biocare AB				
		WO 2001097679 A2	12-27-2001	Thomas J. Lally				
		WO 2002009788 A1	02-07-2002	Herbert P. Jennissen				
		WO 2003043673 A1	05-30-2003	Scil Biomedicals GMBH				
		WO 2005016399 A	02-24-2005	SciMed Life Systems				
		DE 2928007 A1	01-15-1981	Dr. Reiss Guido				
						-		
	_							
			-					

Examiner Signature	/Dennis Heyer/	Date Considered	05/08/2009

EXAMINER Initial if reference considered, whether or not clation is in conformance with MPEP 609. Draw line through clation if not in conformance and not considered, include copy of this form with next communication to applicant. *Applicants unique clation designation number (optional): *See Kinds Codes of the conformation o

SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Substitute	for form 1449B/PTC	,		Complete if Known			
	DREATION	D. C	OL OCUPE	Application Number	10/598,698		
			CLOSURE	Filing Date	July 14, 2006		
STATEMENT BY APPLICANT				First Named Inventor	Klaus Hellerbrand		
١,				Art Unit			
(Use as many sheets as necessary)			necessary)	Examiner Name			
Sheet	4	of	5	Attorney Docket Number	79650 - 341358		

Examiner	Cita	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Τ²
		WHARTON et at., "Drosophilia 60A gene, another transforming growth factor β family member, is closely related to human bone morphogenetic proteins," <i>Proc. Natl. Acad. Sci. USA</i> , Volume 88, pp. 9214-9218, 1991	
		SHAH et al., "Mechanism of BMP-2 stimulated adhesion of osteoblastic cells to titanium alloy," Biology of the Cell, Volume 91, pp. 131-142, 1999	
		WOZNEY et al., "Bone Morphogenetic Protein and Bone Morphogenetic Protein Gene Family in Bone Formation and Repair," Clinical Orthopaedics and Related Research," Number. 348, pp. 28-37, 1998	
		WOZNEY et al., "Novel Regulators of Bone Formation: Molecular Clones and Activities," Science, Volume 242, pp. 1528-1534, 1988	
		WEEKS et al., "A Maternal mRNA Localized to the Vegetal Hemisphere in Xenopus Eggs Codes for a Growth Factor Related to TGF-β," Cell, Volume 51, pp. 881-887, 1987	
		VOGGENREITER et al., * Assesment of the Biological Activity of Chemically Immobilized rhBMP-2 on Titanium surfaces In vivo, * Matwiss u. Werkstofflech., Volume 32, pp. 942-948, 2001	
		UNVERDORBEN et al., "Comparisons of a Silicon Carbide Coated Stent versus a Noncoated Stent in Humans: The Tenax™-versus Nir ™-Stent Study (TENISS)," Journal of Interventional Cardiology, Volume 18, Number 4, pp. 325-333	
		TSUI et al., 'Piasma sprayed hydroxyapatite coatings on titanium substrates, Part 2: optimisation of coating properties," Biomaterials, Volume 19, pp. 2031-2043, 1998	
		STORM et al., "GDF5 Coordinates Bone and Joint Formation during Digit Development," Developmental Biology, Volume 209, pp. 11-27, 1999	
		SCHNAAR et al., "Adhesion of Chicken Hepatocytes to Polyacrylamide Gets Derivatized with N- Acetylglucosamine," The Journal of Biological Chemistry, Volume 253, Number 21, pp. 7940-7951, 1978	
		SCHMITT et al., "Bone Morphogenetic Proteins: An Update on Basic Biology and Clinical Research," Journal of Orthopsedic Research, Volume 17, pp. 289-278, 1999	
		SAMPATH et al., "Bovine Osteogenic Protein Is Composed of Dimers of OP-1 and BMP-2A, Two Members of the Transforming Growth Factor-p Superfamily," <i>The Journal of Biological Chemistry</i> , Volume 285, Number 22, pp. 13188-13205, 1990	
		PADGETT et al., "A transcript from a <i>Drosophila</i> pattern gene predicts a protein homologous to the transforming growth factor- β family," <i>Nature</i> , Volume 325, pp. 81-84, 1987	
		OZKAYNAK et al., Osteogenic Protein-2: A New Member of the Transforming Growth Factor-9 superfamily expressed early in embryogenesis, The Journal of Biological Chemistry, Volume 267, Number 35, pp. 25220-25227, 1992	
		MASSAGUÉ, "The Transforming Growth Factor-β Family," Annu. Rev. Cell Biol., Volume 6, pp. 597-641, 1990	
		LYONS et al., "Vgr-1, a mammalian gene related to Xenopus Vg-1, is a member of the transforming growth factor β gene superfamily," Proc. Natl. Acad. Sci. USA, Volume 86, pp. 4554-4558, 1989	

Examiner /Dennis Heyer/	Date Considered	05/08/2009
-------------------------	--------------------	------------

*EXAMINET: Initial if reference considered, whether or not calation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered include copy of this form with next communication to applicant.

^Applicant's unique citation designation number (optional). *Applicant is to place a check mark here if English language Translation is attached. SEND TO: Commissioner for Patients, P.O. Box 1450, Alexandrid, VA 22313-1450.

ESD (10.08) SD(09b(07.08)

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT				Complete if Known		
				Application Number	10/598,698	
				Filing Date	July 14, 2006	
				First Named Inventor	Klaus Hellerbrand	
				Art Unit		
(Use as many sheets as necessary)				Examiner Name		
Sheet	5	of	5	Attorney Docket Number	79650 - 341358	

Contaction.	104	NON PATENT LITERATURE DOCUMENTS	
Examiner Initials *	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
		LIND, 'Growth factors: Possible new clinical tools: A Review," Acta Orthop Scand, Volume 67, Number 4, pp. 407-417, 1996	
		OZKAYNAK et al., "OP-1 cDNA encodes an osteogenic protein in the TGF-β family," The EMBO Journal, Volume 9, Number 7, pp. 2085-2093, 1990	
		OZBEK et al., "Coronary Implantation of Silicone-Carbide-Coated Palmaz-Schatz Stents in Patients With High Risk of Stent Thrombosis Without Oral Anticoagulation," Cathetenzation and Cardiovascular Diagnosis, Volume 41, pp. 71-8, 1997	
		NISHITOH et al., "Identification of Type I and Type II Serine/Threonine Kinase Receptors for Growth/Differentiation Factor-5," The Journal of Biological Chemistry, Volume 271, Number 35, pp. 21345-21352, 1996	
		LICHTINGER et al., "Osseointegration of Titanium Implants by Addition of Recombinant Bone Morphogenetic Protein 2 (rhBMP-2)," Mat. wiss. u. Werkstofftech., Volume 32, pp. 937-941, 2001	
		LI et al., "Mineral Dusts Oxidize Methionine Residues: Probable Mechanism of Inactivation of Alpha-1- Antitrypsin," Ann. occup. Hyg., Volume 41, Supplement 1, pp. 379-383, 1997	
		KATAGIRI et al., "The Non-Osteogenic Mouse Pluripotent Cell Line, C3H10T1/2, is Induced to Differentiate into Osteoblastic Cells by Recombinant Human Bone Morphogenetic Protein-2." Blochemical and Biophysical Research Communications, Volume 172, Number 1, pp. 295-299, 1990	
		JENNISSEN, "Ultra-hydrophile metallische Biomaterialien," Volume 2, Number 1, pp. 45-53, 2001	abstract included
		HOFMA et al., "Recent Developments in Coated Stents," Current Interventional Cardiology Reports, Volume 3, pp. 26-28, 2001	
		ENDO, "Chemical Modification of Metallic Implant Surfaces with Biofunctional Proteins (Part 1) Molecular Structure and Biological Activity of a Modified NITI Alloy Surface," <i>Dental Materials Journal</i> , Volume 14, Number 2, pp. 185-198, 1995	
		BROWN, "Incomplete Labeling of Pharmaceuticals: A List of "Inactive" Ingredients," The New England Journal of Medicine, Volume 309, Number 7, pg. 439, 1982	
		CELESTE et al., "Identification of transforming growth factor β family members present in bone-inductive protein purified from bovine bone," <i>Proc. Natl. Acad. Sci., USA</i> , Volume 87, pp. 9843-9847, 1990	
		ALBREKTSSON, 'Hard tissue response,' Handbook of Biomaterial Properties, "Chapter 3, pp. 500-512, 1998	
		BLACKBURN et al., "Carbohydrate-specific Cell Adhesion Is Mediated by Immobilized Glycolipids," The Journal of Biological Chemistry, Volume 258, Number 2, pp. 1180-1188, 1983	
		AMERICAN ACADEMY OF PEDIATRICS, COMMITTEE ON DRUGS, "Inactive' Ingredients in Pharmaceutical Products," Pediatrics, Volume 76, Number 4, pp. 635-643, 1985	
		International Conference on Harmonization, Topic Q3C, Impurities Residual Solvents, www.emea.eu.int, March 1998	
		International Search Report and Written Opinion of International Application Number PCT/EP2005/002506, filed March 3, 2005, both mailed September 14, 2005	

Examiner Signature	Date Considered	

"EXAMINEE: Initial if reference considered, whether or not citation is in conformance with MPEP 600. Draw line through citation if not in conformance and not considered include copy of this form with next communication to applicant.

'Applicant's unique citation designation number (rodoncal). "Applicant is to place a check mark here if English language Translation is attached.
SEND TO Commissioner for Pattents, P.O. Box 1450, Alexandria, VA 22313-1450.

fb-us.1755221.01

J